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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/718,685	11/21/2000	Eugeni A. Vaisberg	CYTOP007C2	5849
22434	7590	06/15/2004	EXAMINER	
BEYER WEAVER & THOMAS LLP			MAHATAN, CHANNING	
P.O. BOX 778			ART UNIT	
BERKELEY, CA 94704-0778			PAPER NUMBER	
			1631	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/718,685

Applicant(s)

VAISBERG ET AL.

Examiner

Channing S Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-43 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-43 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

REQUEST FOR RECONSIDERATION

A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114.

APPLICANTS' ARGUMENTS

Applicants' arguments, filed 22 March 2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 40-43 and 51.

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

NEW MATTER

Claims 40-43 and 51 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 40 and all claims dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph. The introduction of “code for producing a fingerprint characterizing the manipulated cells, wherein the fingerprint comprises morphological values for the plurality of manipulated cells for each of the plurality of different cell lines” and “statistically comparing said fingerprint against the fingerprint associated with known behaviors in a database” is considered new matter. Applicants’ submit support for the above claim amendments can be found on pages 14, 15, and 24. However, there does not appear to be support for the broadly encompassing language of “producing a fingerprint...” wherein the specification provides for only one methodology of “producing a fingerprint”, but not any others (Refer to below 35 U.S.C. § 112 1st Paragraph Scope of Enablement). Nor does there appear to be support for the broadly encompassing language of “known behaviors in a database”, wherein it is noted page 24 (first full paragraph) with regard to “behaviors” states (Refer to below 35 U.S.C. § 112 2nd Paragraph):

“...permit a correlation to be drawn between similar fingerprints. Such correlations can predict similar behaviors or characteristics with regard to mechanism of action, toxicity, animal model effectiveness, clinical trial effectiveness, patient responses and the like.”

Therefore, the above amendments are considered NEW MATTER.

SCOPE OF ENABLEMENT

Claims 40-43 and 51 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for “producing a fingerprint” from morphological values via a specific algorithm (outlined below), does not reasonably provide enablement for any other

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means for “producing a fingerprint” from morphological values. No guidance, direction, or examples are provided such that one of ordinary skill in the art would have known practice how to the claimed invention commensurate in scope with the claims.

Applicants’ assert a programmer or other technical person could readily create code to capture morphological values, produce a fingerprint, produce a statistical profile, and map the effect of the manipulation based upon the statistical profile. Applicants’ have articulated a brief description of the each element of independent claim 40. Further, Applicants’ state:

“...producing a fingerprint comprising morphological values requires only routine mathematically or algorithmic skill using the teachings of the present specification. Essentially, all that is required is a computational mechanism for grouping or associating the constituent morphological values with another.”

However, Applicants’ arguments are found unpersuasive. It is acknowledged, if given sufficient guidance a programmer could readily create computer code. In the instant case, in order to create computer code that performs a computational mechanism the programmer would at least require guidance as to the operation(s)/function(s) the computer code is intended to achieve; in this case “producing a fingerprint”. The only disclosed method of “producing a fingerprint” is indicated as being:

“Resulting measurements were arranged into a string of numbers and reduced to a pseudo- nucleic acid sequence using following rules: At any given position in the sequence a number was substituted by “t” (a code for thymidine) if its value is among the highest 25% of the values at the corresponding position in the data set, “g” if it is between 50%-25%, “c” if it is between 75% and 50%, and “a” if it belongs to the lowest 25% of values.” (page 45, lines 19-24 of the Specification)

wherein the above pseudo-nucleic acid sequence is assigned to specific measurements of the parameters found in the Table on pages 13-14 (i.e. count, area, perimeter, etc). Figure 13

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illustrates the assignment of pseudo-nucleic acid sequence to these measured parameters and reveals the resulting fingerprints. Therefore, the specification provides only limited guidance to a programmer as to what operation(s)/function(s) the computer code is to accomplish. For example, if a programmer is to create “code for producing a fingerprint...” (as broadly claimed); the programmer would be required to derive specific criteria(s)/parameter(s) and operation(s)/function(s) for the computer code. In the instant case, for such a derivation to occur one of skill in the art (i.e. programmer) would be required to make independent decisions and judgements regarding: 1) derive the initial governing parameters; 2) ascertain the operation(s)/function(s) by which the computer code is process the measurement of said parameters; and 3) test and validate the operation(s)/function(s) by which the computer code processes said measurement to produce a fingerprint. Applicants are directed to Fields, Wilkinson, and Kende v. Conover and Woodward [170 USPQ 276; How-to-Make Requirement section] which states:

"the description must place the invention in the possession of the public as fully as if the art or instrument itself had been practically and publicly employed. In order to accomplish this, it must be so particular and definite that from it alone, without experiment or the exertion of his own inventive skill, any person versed in the art to which it appertains could construct and use it."

Such independent decisions, judgments, tests, and validation are not considered to be routine experimentation and one of skill in the art practicing the invention would be required to use inventive skill to develop Applicants' other “code for producing a fingerprint”. No other “code for producing a fingerprint” is disclosed. None appear to have been known in the art. Thus, the instant claims embrace more than what is taught in the original disclosure. Therefore, the

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-43 and 50 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claim 40 and all claims dependent therefrom recite the limitation “fingerprints associated with known behaviors in a database” which is vague and indefinite. It is unclear the criteria(s) that establishes “fingerprints” and “known behaviors in a database” to be associated with each other. Applicants can resolve this issue by particularly pointing out the criteria that formulates said association. Additionally, the phrase “known behaviors” is not limited to any particular “known behavior”, but inclusive of anything (i.e. cellular motility) to the extent that is unclear what these known behaviors are intended to encompass (Refer to above 35 U.S.C. § 112 1st Paragraph New Matter). Clarification of the metes and bounds, via clearer claim language, is requested.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

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in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 872-9306.

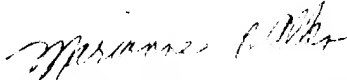
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina M. Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date:

Examiner Initials:


MARIANNE P. ALLEN 6/10/09
PRIMARY EXAMINER
